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| 10/537,266 | 06/01/2005 | Yasuo Tano | 124098 | 1045 |
| 25944 7590 01/11/2010 OLIFF & BERRIDGE, PLC P.O. BOX 320850 ALEXANDRIA, VA 22320-4850 | | | | |
| EXAMINER | | | | |
| LAVERT, NICOLE F | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,266

Applicant(s)

TANO ET AL.

Examiner

NICOLE F. LAVERT

Art Unit

3762

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 6/1/05
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support within the specification for the claim limitation "...the signal wires each being covered with an insulating material with high biocompatibility and having first regions bundled up and second regions individually foldable between the first regions and the electrode," in combination with the other elements in the claim.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Yagi (US 2004/0102843) in view of Byers et al. (US 4,969,468) and Barsne (US 6,720,497).

Yagi discloses an artificial vision system (e.g., Fig 1, 1) comprising: an external device to be disposed outside a body of a patient (e.g., Fig 1, 2); an image pickup device (e.g., Fig 1, 4); and an image processing device (e.g., Fig 1, 9) which generates a stimulation signal by processing an image captured by said image pickup device; an internal, implanted device (e.g., Fig 1, 3) including: a receiving device which receives a stimulation pulse signal and converts it into an electrical stimulation pulse signal (see Figure 1, 'reception'); and a plurality of electrodes (e.g., Fig 1, 11) which outputs the electrical stimulation pulse signal that is generated based on the image captured by the image pick up device thereby enabling the patient to visually recognize the image captured by said image pick up device (e.g., [0028]-[0030], [0053]-[0054] & [0059]).

Yagi discloses the claimed invention having an artificial vision system including a plurality of electrodes except wherein said system includes electrodes with a needle-shaped end that are adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla of the eye and a plurality of signal wires which individually connect each said electrode and the receiving device covered with an insulating material with high biocompatibility and having first regions bundles up and second regions individually foldable between the first regions of the electrode. Byers et al. teaches that it is known to use electrode arrays for

electrically stimulating nerve fibers in which said arrays comprises needle-like contacts that are disposed along the optic nerve or the paths where the optic nerve enters the cortex, in which Byers et al. is also capable of meeting the functional use recitations presented in the claim of being "...implanted in the eyes so as to stick in a bundle of nerves fibers of an optic papilla..." since the disclosed needle electrodes can be placed and will stick in claimed locations [e.g., (col 7, ln 33-53) & (col 15, ln 4-13)]. Note that the optic papilla is the portion of the optic nerve formed by retinal ganglion cells axons as they enter said optic nerve, in which the optic papilla is the location of the eye along the pathways of the optic nerve. Barsne teaches that it is known to use a medical electrode cable having an exterior, tubular insulating sheath (e.g., element 8) containing a number of adjacent wires arranged parallel to said sheath [e.g., (col 4, ln 1-20) & (Fig 1)]. Note that the disclosed tubular, insulative sheath is capable of providing the plurality of wires having the first, bundled regions and the individually, foldable second regions as is instantly claimed (e.g., Fig 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Yagi with the needle electrode array adapted to be disposed on the optic nerve comprising conductors extending from said needle electrodes to other electrical circuitry as taught by Byers et al. and the plurality of wires enveloped by an insulative, tubular sheath as taught by Barsne, since such a modification would provide the artificial vision system including a plurality of electrodes with a needle-shaped end that are adapted to be implanted in the eye so as to stick in a bundle of nerve fibers of an optic papilla of the eye and a plurality of signal wires which individually connect each said electrode and the receiving device covered with an insulating material with high biocompatibility and having first regions bundles up and second regions individually foldable between the first

regions of the electrode for providing the predictable results pertaining to providing a needle-shaped electrode used to penetrate into the optic nerve of a patient for effectively making electrical contact within the nerve fibers of said optic nerve so as to enhance optical functions of a patient (e.g., Byers, col 15, ln 4-13) and providing the results pertaining to providing an electrode cable comprising a plurality of wires suitable for use as an electrical connection between an electrical stimulating device and connectable to the proximal end of the cable an electrode(s) connected to the distal end of the cable, wherein said plurality of wires are shielded from stray electrical energy that may be harmful to a patient by way of an insulative, tubular sheath (e.g., Barsne, col 1, ln 6-14).

Response to Arguments

4. Applicant's arguments filed 21 September 2009 have been fully considered but they are not persuasive. The Applicant argues that the primary reference, Yagi, fails to disclose an external device adapted to be disposed outside a body of a patient and that the secondary reference, Byers et al., additionally fails to disclose an electrode covered with an insulating material with high biocompatibility and having first regions bundles up and second regions individually foldable between the first regions and the electrodes. In addition, the Applicant argues that since Byers et al. was not intended to be used in the eyeball, and therefore there would be no reasonable rationale for modifying Yagi based on Byers. The Examiner disagrees with the above arguments and further points out that Yagi discloses an artificial eye system comprising an extracorporeal unit (e.g., element 2) which is mounted outside a user's body therefore providing the claimed external device {e.g., [0053] & (Fig 1)}. Also, the Examiner notes that the argument pertaining to Byers et al. not disclosing an electrode covered with an

insulative material...etc., is moot since the claimed invention calls for a plurality of wires being "...covered with an insulating material..." versus an electrode. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Byers et al. teaches an electrode employed for electrically sensing or stimulating biological tissue, i.e., the disclosed electrode is capable of being used to sense and stimulate the eyeball of a patient (e.g., Byers, co 1, ln 13-24).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762